

Atty. Dkt. No. 035879-0165

Applicant:

Thomas E. WAGNER et al.

Title:

**AAV ITR-MEDIATED MODULATION** 

Appl. No.:

10/669,641

Filing Date: 9/25/2003

Examiner:

Celine X. Qian

Art Unit:

1636

## INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.

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## TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

## RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

The foregoing documents were cited in the International Search Report in Applicants' International Application. A copy of the International Search Report setting forth the portion of each reference considered relevant by the examiner is attached.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date: August 3, 2004

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MODIFIED PTO/SB/08 (08-00)

PADEM

Approved for use through 10/31/2002. OMB 0651-0031

1636

Celine X. Qian

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STATEMENT BY APPLICANT	Filing Date	9/25/2003	AUU U 3 2004
Date Submitted: August 3, 2004	First Named Inventor	Thomas E. WAGNER	

Group Art Unit

**Examiner Name** 

Attorney Docket Number

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				U.S. PATENT DOCUMENTS		
Examiner Initials*	0:1-	U.S. Patent Document			Date of Publication of	Pages, Columns, Lines, Where Relevant
	No.1 Nu	Number	Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	For Office <sup>3</sup>	eign Patent D Number <sup>4</sup>	Oocument Kind Code <sup>5</sup> (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т6

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	B1	Roli K. HIRATA et al., "Design and Packaging of Adeno-Associated Virus Gene Targeting Vectors", Journal of Virology, May 2000, Vol. 74, No. 10, pgs. 4612-4620.				
**************************************	B2	Jinsong REN et al., "Spectral and physical characterization of the inverted terminal repeat DNA structure from adenoassociated virus 2", Nucleic Acids Research, 1999, Vol. 27, No. 9, pgs. 1985-1990.				
	В3	C. C. YANG et al., "Cellular Recombination Pathways and Viral Terminal Repeat Hairpin Structures are Sufficient for Adeno-Associated Virus Integration in Vivo and In Vitro", Journal of Virology, December 1997, Vol. 71, No., 12, pgs. 9231-9247.				
	B4	Xu-Shan WANG et al., "Adeno-Associated Virus Type 2 DNA Replication In Vivo: Mutation Analyses of the D Sequence in Viral Inverted Terminal Repeats", Journal of Virology, April 1997, Vol. 71, No. 4, pgs. 3077-3082.				
	B5	Matthew D. WEITZMAN et al., "Interaction of Wild-Type and Mutant Adeno-Associated Virus (AAV) Rep Proteins on AAV Hairpin DNA", Journal of Virology, April 1996, Vol. 70, No. 4, pgs. 2440-2448.				
	B6	Kenneth RAJ et al., "Virus-mediated killing of cells that lack p53 activity", Nature, August 30, 2001, Vol. 412, pgs. 914-917.				
	B7	Xiao XIAO et al., "A Novel 165-Base-Pair Terminal Repeat Sequence is the Sole <i>cis</i> Requirement for the Adeno-Associated Virus Life Cycle", Journal of Virology, February 1997, Vol. 71, No. 2, pgs. 941-948.				
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Examiner		Date	
Signature	·	Considered	

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.